

Attorney Docket No.: KBI-0022
Inventors: Ranganathan, Natarajan
Serial No.: 10/803,211
Filing Date: March 18, 2004
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REMARKS

Claims 1, 2, and 4 are pending in the instant application. Claims 1, 2, and 4 have been rejected. Claim 1 has been amended. No new matter has been added by this amendment. Reconsideration is respectfully requested in light of the following remarks.

I. Rejection of Claims under 35 U.S.C. §103

Claims 1, 2 and 4 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Reddy et al. (U.S. Patent No. 6,080,401). The Examiner suggests that Reddy et al. indicates a range of 0.1 to 400 mg bacteria may be present, indicating that such an amount of bacteria would easily be optimized by one of ordinary skill in the art. Applicant respectfully disagrees.

MPEP 2144.05 indicates that a particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation.

As disclosed at page 7 (lines 25-30) of the instant specification, Applicant has appreciated that a composition containing a higher number of viable *Streptococcus thermophilus* cells (i.e., 10^{10} to 10^{11} cfu) than both *Lactobacillus acidophilus* and *Bifidobacterium longum* (i.e., 10^9 to 10^{10} cfu), effectively decreases both BUN and creatinine levels. As such, Applicant has demonstrated that the amount of viable *S. thermophilus* relative to *L. acidophilus* and *B. longum* is a result-effective variable which decreases both BUN and creatinine levels.

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Thus, in an earnest effort to facilitate the prosecution of the instant application, Applicant has amended claim 1 to highlight the use of a higher number of viable *Streptococcus thermophilus* cells (i.e., 10^{10} to 10^{11} cfu) relative to *Lactobacillus acidophilus* and *Bifidobacterium longum* (10^9 to 10^{10} cfu) in order to reduce both BUN and creatinine levels. Support for this amendment is found at page 7 (lines 27-30) which states "*Lactobacillus acidophilus* is of particular use between 10^9 to 10^{10} cfu, whereas *B. longum* is preferred for use between 10^9 to 10^{10} cfu, and *S. thermophilus* between 10^{10} to 10^{11} cfu."

While Reddy et al. teach compositions containing probiotic bacteria in an amount ranging from 0.1 to 400 mg, this reference does not teach or suggest that the amount of each bacterium, in particular a higher number of viable *Streptococcus thermophilus* cells, in a composition is a result-effective variable which provides for a decrease in both BUN and creatinine levels. Further, Reddy et al. do not teach or suggest the use of *S. thermophilus*, or any bacterium, at 10^{10} to 10^{11} colony forming units. Moreover, while Reddy et al. disclose the use of viable probiotic bacteria, this reference does not indicate whether 100% of the bacteria in the indicated milligram quantities are viable. Accordingly, the milligram quantities disclosed by Reddy et al. are only indicative of total bacterial cell weight (dead and alive), not the number of viable bacteria, a quantity generally expressed as colony forming units.

Because the cited reference neither teaches nor suggests the claimed composition, this reference cannot be held to make the present invention obvious. It is therefore respectfully requested that this rejection be reconsidered and withdrawn.

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II. Conclusion

Applicant believes that the foregoing comprises a full and complete response to the Advisory Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,



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